K110055

APR - 5 2011

4. 510(k) Summary according to 807.92

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Reverse Medical Corporation is providing the summary of Substantial Equivalence for the ReFlex™ Guide Catheter.

4.1 Sponsor /Applicant Name and Address

Reverse Medical Corporation
13900 Alton Parkway
Suite 123
Irvine, CA 92618

4.2 Sponsor Contact Information

Jeff Valko
President/CEO
Phone: 949-215-0660
Fax: 949-215-0661
email: jvalko@reversemed.com

4.3 Date of Preparation of 510(k) Summary

March 10, 2011

4.4 Device Trade or Proprietary Name

ReFlex™ Guide Catheter

4.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY)

4.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Device	Name of Manufacturer (Town, State)	510(k) Number
Penumbra Neuron™ Intracranial Access System	Penumbra, Inc. Alameda, CA	K070970
HD Guide Catheter	Concentric Medical, Inc. Mountain View, CA	K090335

510(k) Summary according to 807.92 (continued)

4.7 Device Description

The ReFlex™ Guide Catheter is a single lumen, flexible, variable stiffness composite catheter. The catheter shaft has a hydrophilic coating to reduce friction during use. The ReFlex™ Guide Catheter shaft is visible under fluoroscopy. The ReFlex™ Guide Catheter dimensions are included on the individual device label. The ReFlex™ Guide Catheter inner lumen can accommodate guidewires up to 0.038 inches in diameter to aid in placement of the catheter system.

The proximal end of the ReFlex™ Guide Catheter has a luer fitting to allow attachment of accessories and infusion of liquids through the system. The ReFlex™ Guide Catheter is offered in various sizes to accommodate physician preferences and anatomical variations. The catheter is provided sterile, non-pyrogenic, and is intended for single use only.

4.8 Intended Use

The Reverse Medical ReFlex™ Guide Catheter is indicated for the introduction of interventional devices into the peripheral, and neuro vasculature.

4.9 Comparison to Predicate Devices

	Penumbra Neuron™ Intracranial Access System	HD Guide Catheter	ReFlex™ Guide Catheter
510(k) Number	K070970	K090335	TBD
Classification	Class II, DQY	Class II, DQY	Class II, DQY
Indication	The ... is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The ... is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems.	The ... is indicated for the introduction of interventional devices into the peripheral, , and neuro vasculature.
Materials			
- Shaft Materials	PTFE lined nylon/polyurethane catheter, with hydrophilic coating	PTFE lined polymeric catheter with hydrophilic coating	PTFE lined polymeric catheter, with hydrophilic coating
- Catheter shaft support	Stainless Steel	Stainless Steel	Nitinol
- Proximal End Configuration	Luer Hub	Luer Hub	Luer Hub
- Radiographic markers / Radiopacity	• Radiopaque marker at distal tip	• Radiopaque marker at distal tip	• Radiopaque marker at distal tip

510(k) Summary according to 807.92 (continued)

4.9 Comparison to Predicate Devices (continued)

	Penumbra Neuron™ Intracranial Access System	HD Guide Catheter	ReFlex™ Guide Catheter
- Packaging	Catheter attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton	Catheter in polyethylene hoop inside PET/PE/Tyvek pouch inside SBS carton	Catheter in polyethylene hoop attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton
Packaged Accessory Devices	Packaged with an rotating hemostatic valve (RHV)	Packaged with an rotating hemostatic valve (RHV)	Not Applicable
Sterilization	EtO	EtO	EtO

4.10 Summary of Non-clinical Data

4.10.1 Biocompatibility and Sterilization

The ReFlex™ Guide Catheter is classified as Externally Communicating Devices, Circulating Blood, Limited Contact (≤ 24 hours). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1 guidelines "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The ReFlex™ Guide Catheter successfully passed all of the following biocompatibility tests:

Test	Method
Cytotoxicity	L929 MEM Elution Test
Sensitization	Kligman Maximization
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test
Systemic Toxicity (Acute)	ISO Acute Systemic Injection Test
Hemocompatibility	Complement Activation
	Hemolysis
	Inactivated Partial Thromboplastin Time Test
	In vivo thrombogenicity
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test
EtO Residuals	Ethylene oxide and Ethylene chlorohydrins residuals

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

510(k) Summary according to 807.92 (continued)
4.10.2 Design Verification (Bench-Top Testing)

The physical, mechanical and performance testing of the ReFlex™ Guide Catheter demonstrates that the product is substantially equivalent to the currently marketed predicate devices. Design Verification testing was conducted to evaluate the physical and mechanical properties of the ReFlex™ Guide Catheter. All studies were conducted in accordance with Reverse Medical Design Control procedures. All testing was performed on units which were sterilized and met all inspection criteria. Tests on the ReFlex™ Guide Catheter included:

Verification and Test Summary

***In vitro* Tests**	**Result**
Dimensional and Visual Inspection	Met established criteria
Guidewire Compatibility	Met established criteria
Torque Response	Met established criteria
Torque Strength	Met established criteria
Kink Resistance	Met established criteria
Flexibility Test	Met established criteria
Tensile Strength	Met established criteria
Catheter Leak Test (Liquid Leakage)	Met established criteria
Catheter Leak Test (Air Leakage)	Met established criteria
Dynamic Pressure Test	Met established criteria
Static Burst Test	Met established criteria
Aspiration Test	Met established criteria
Hub Gauging	Met established criteria
Corrosion Resistance	Met established criteria
USP Particulate Test	Met established criteria
Navigation and Accessibility Capabilities *in vitro*	Met established criteria
***In vivo* Tests**	**Result**
System Deliverability, Compatibility, Visibility and Aspiration Performance	Met established criteria
Acute histopathology of treated vessels	Met established criteria
Biocompatibility testing	Met established criteria

The physical, mechanical and performance testing of the subject ReFlex™ Guide Catheter demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate devices.

4.11 Substantial Equivalence

The performance of the ReFlex™ Guide Catheter in this submission demonstrates that the product is substantially equivalent to the performance of the predicate devices. The equivalence was shown through comparison of component materials and specification, performance and biocompatibility testing and sterilization validation.

The ReFlex™ Guide Catheter is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate devices. Differences between the devices do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Reverse Medical Corporation
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th St. NW
Buffalo, MN 55313

APR - 5 2011

Re: K110055
Trade/Device Name: ReFlex™ Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 18, 2011
Received: March 21, 2011

Dear Mr. Job

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act.. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use

510(k) Number (if known): K110055

Device Name: Reverse Medical ReFlex™ Guide Catheter

Indications for Use:

The Reverse Medical ReFlex™ Guide Catheter is indicated for the introduction of interventional devices into the peripheral, and neuro vasculature.

Prescription Use X AND/OR Over the Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110055